K100919

Section 9

Attachment 4

DEC 16 2011

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical
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Contact person: Randi Hauerberg, Regulatory Affairs Manager
Date prepared: March 29, 2010

Trade name: Ultrasound Scanner Pro Focus 2202
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1560)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
B-K Medical Ultrasound Scanner Pro Focus 2202, K043524

Device description:

Pro Focus 2202 supports the following scanning modes and combinations thereof:
B-mode (incl.Tissue Harmonic Imaging), M-mode, PWD mode, CFM mode, Amplitude (Power) Doppler mode.
The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.
An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.
An optional 3-D module can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.
An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

Transducers
Transducers are linear arrays, convex arrays, phased arrays and mechanical sector.
The patient contact materials are biocompatible.
All transducers used together with Pro Focus 2202 are Track 3 transducers.

Acoustic output
The system controlling the Acoustic Output in the modified Pro Focus 2202 is the same as the system in Pro Focus 2200. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta $\leq$ 720 mW/cm^2 and MI $\leq$ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI $\leq$ 6.0

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Clinical measurement accuracy
Clinical measurements and calculations are described and accuracies are provided in the User Information.

Thermal, mechanical and electrical safety.
The scanner Pro Focus 2202 has been tested by a recognized Certified Body.

Acoustic Output Reporting
The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 9, 2008"

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

Summary of Technological Characteristics – Predicate Device Compared to Modified Device

	Predicate device K043524, Ultrasound scanner Pro Focus 2202	**Modified device, Ultrasound scanner Pro Focus 2202**
Modes of operation Ref.: [1] Appendix G	B, M, PWD, CFM [1)] and combinations Tissue harmonic imaging.	B, M, PWD, CFM [1)+2)] and combinations Tissue harmonic imaging.
Intended Use: Indications For Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Abdominal Cardiac Fetal (incl Obstetrics) Intraoperative Transurethral Neurosurgery Pediatrics Transrectal Small Parts (organs) Transvaginal Peripheral vascular Muskulo-skeletal (conventional and superficial)
Features	ECG (not monitoring)	ECG (not monitoring)

1) CFM= Color Flow Mapping=Color Doppler and Amplitude (Power) Doppler.
2) Includes Vector Flow Imaging (modified device)

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Technological characteristics compared to the predicate device
The predicate device has the same major technological characteristics as the subject device described above.
Minor differences consist: Optional Vector Flow Imaging (VFI) module.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Randi Hauerberg
Regulatory Affairs Manager
B-K Medical ApS
Mileparken 34
DK-2730 HERLEV
DENMARK

DEC 16 2011

Re: K100919
Trade/Device Name: Ultrasound Scanner Pro Focus 2202
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 9, 2011
Received: September 12, 2011

Dear Mr. Hauerberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100919

Device Name: **Ultrasound Scanner Pro Focus 2202**

Indications for Use:

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD,CWD, Color Doppler, Vector Flow Imaging and combined mode imaging.
Signal analysis and display.
Guidance of biopsy needles, geometrical measurements and calculation of parameters.
Non monitoring ECG for superimposing the ultrasound information.
An optional 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

Clinical applications: Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics,Transrectal, Small organs, Transvaginal, Musculoskeletal.

Details on specific Indication for Use forms

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100919

Diagnostic Ultrasound Indications for Use Form

System: 2202

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	Tissue-and contrast harmonic imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify 1)	Continous Wave)
Ophthalmic										
Fetal 2)		P	P	P	P	P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological		P	P	P	P	P	P		P	
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)		P	P	P	P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	
Transesophageal										
Transrectal		P	P	P	P	P	P		P	
Transvaginal		P	P	P	P	P	P		P	
Transurethral		P	P	P	P	P	P		P	
Intravascular										
Peripheral Vascular		P	P	P	P	N[3]	P		P	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P	
Musculo-skeletal Superficial		P	P	P	P	P	P		P	
Other (specify)										

N= new indication; P= previously cleared by FDA **K043524** E= added under Appendix E

Additional Comments:
1) B+M, B+D, B+C, B+D+C.
B mode includes Tissue Harmonic Imaging.
D is PWD,
C is Color Doppler.
2) Fetal is often called Obstetrics
3) Vector Flow Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Prescription Use (Per 21 CFR 801.109)

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510K K100919